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ABSTRACT

The following standards are affirmed by the American Medical Technologists organization: (1) regardless of the size of the laboratory setting, the patient deserves the highest quality of laboratory service available; (2) certified personnel should be employed by physicians in office laboratories; (3) quality control should be mandatory and supported by an appropriate proficiency-testing program; (4) regardless of the setting, all laboratories should be measured against one set of regulations; (5) the kind and amount of testing done in a physician's office laboratory should determine the type of certified personnel necessary to do the job; (6) those responsible for the management of the physician's office laboratory should recognize and acknowledge testing limitations and use the resources of reference laboratories when necessary; (7) medical technologists should be used as consultants to physician's office laboratories when the scope of testing performed and equipment utilized go beyond the capability of the individuals employed in the facility; and (8) the laboratory should be directed and supervised by a physician, a recognized Medicare laboratory director, or a certified medical technologist. Five important issues are: (1) type of tests to be performed and by whom; (2) quality control and proficiency testing; (3) minimum personnel qualifications; (4) suggestions on how criteria could or should be enforced and by whom; and (5) in-house testing or the use of reference labs. (CML)

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# AMT's Position on Physician's Office Laboratories

## PREFACE

Numerous factors have contributed to the current interest in physician's office laboratories. These include the recent cost containment legislation, DRG's, Medicare reimbursement, alleged unreliable results from some physicians' office laboratories, laboratory organizations representing generalist laboratory practitioners helping members find new job opportunities in a changing laboratory market and the growth of laboratory testing conducted in physician's office laboratories.

## INTRODUCTION

Since its inception in 1939 AMT has championed the cause of a medical technologist directing a clinical laboratory. It pioneered the certification of laboratory directors and supervisors, and by virtue of education and/or experience and examination laboratory personnel could have a meaningful career ladder to advance in the profession. No level of technical or administrative employment should be denied the competent practitioner.

As early as 1971 AMT initiated a program for certifying medical assistants, and the first certifying examination was approved and available for the March, 1972 proctoring date. Medical assistants' principal source of employment is the physician's office. The medical assistants had, as part of their training, a component devoted to laboratory testing. While that portion of the medical assistant training was limited to performing some basic tests, AMT believed that it could be instrumental in influencing the type of training offered to these students to better equip them to provide limited but quality laboratory services to the physician.

As a result of this interest, and in cooperation with the Accrediting Bureau of Health Education Schools (ABHES) accreditation of medical assistant schools became a reality.

The Accrediting Bureau of Health Education Schools is listed as a nationally recognized accrediting agency by the U.S. Department of Education to accredit private and proprietary health education institutions and specialized programs for medical laboratory technician and medical assistant education. The Bureau is also recognized by the Council on Postsecondary Accreditation to accredit medical laboratory technician and medical assistant education programs in the private sector.

The AMT certification process which includes medical assistant certification in addition to certification for medical technologists and medical laboratory technicians earned it Category A membership on the National Commission for Health Certifying Agencies.

AMT's involvement in one segment of physician office laboratory practice, i.e., certification of medical assistants, prompted AMT President Rebecca Moretz, MT (AMT) to mobilize both the AMT Board of Directors and the Registered Medical Assistants (RMA) Executive Board to develop an AMT position statement on physician's office laboratory services. She instructed the Boards to address the following areas:

1. Type of tests to be performed and by whom
2. Quality Control
3. Proficiency Testing
4. Type of equipment to be used
5. Minimum personnel qualifications to be tied into #1
6. Consultants and their role
7. How criteria could or should be enforced and by whom
8. The use of reference labs—when?

This position paper would reinforce AMT's interest in the quality of laboratory service provided to consumers as evidenced by AMT's program of certification of personnel.

## AFFIRMATION

1. Regardless of the size of the laboratory setting the patient deserves the highest quality of laboratory service available.
2. Certified personnel should be employed by physicians in office laboratories.
3. Quality Control should be mandatory and supported by an appropriate proficiency testing program.
4. Regardless of the setting all laboratories should be measured against one set of regulations.
5. The kind and amount of testing done in a physician's office laboratory should determine the type of certified personnel necessary to do the job.
6. Those responsible for the management of the physician's office laboratory should recognize and acknowledge testing limitations and use the resources of references laboratories when necessary.
7. Medical Technologists should be utilized as consultants to physician's office laboratories when the scope of testing performed and equipment utilized go beyond the capability of the individuals employed in the facility.
8. The laboratory should be directed/supervised by a physician, a recognized Medicare laboratory director, or a certified medical technologist.

## THE ISSUES

A. *Type of Tests to Be Performed and by Whom*

There should not be any limitations on the type of tests performed in the physician office laboratory provided the personnel, equipment and standards for quality testing are available.

1. A certified medical assistant should be capable of providing accurate results when basic tests required by the physician are performed. The services of a consulting certified medical technologist should be utilized on a regular basis. If a full range of testing is provided the services of a certified medical technologist should be mandatory.

2. A certified medical laboratory technician should be capable of handling a variety of testing procedures requiring a limited exercise of independent judgment and discretion. The services of a consulting certified medical technologist should be utilized on a regular basis. If a full range of testing is provided the services of a certified medical technologist should be mandatory.

B. *Quality Control/Proficiency Testing*

Every physician's office laboratory regardless of size should maintain a quality control program (daily on tests →

performed). The facility should also subscribe to a Proficiency Testing Program to cover all tests performed in the physician's laboratory.

C. *Minimum Personnel Qualifications*

Personnel certified by organizations that are Category A Members of the National Commission for Health Certifying Agencies should be utilized in addition to those medical technologists who have successfully passed the Proficiency Examination administered by the U.S. Department of Health and Human Services. Other certifiers of medical laboratory personnel should show evidence that the certifying body meets the criteria of NCHCA.

D. *Suggestions on How Criteria Could or Should Be Enforced and by Whom*

AMT supports the concept that all laboratories, regardless of size and location—including those operated by local, State and Federal governments, should conform to a single set of standards, such as the Medicare Standards for Independent Laboratories.

It is AMT's suggestion that each state conduct a statewide registration of physician's office laboratories and charge an appropriate fee to cover the cost of this annual registration. Such fees should be utilized to support a five year study of these facilities to determine the quality of service provided. The study would monitor the following:

1. Size of setting/personnel/equipment/tests involved.
2. Quality Control and Proficiency Testing data as submitted to the Division/Bureau of Laboratories for analysis. Evidence of substandard performance would result in an on-site consultative visit, at the offending laboratory's expense.
3. Testing charges and costs.

Each state could analyze its data and compare it with the data/analyses from other states. A coordinating body, such as the Council of State Governments, could study the data and issue a report and recommendations regarding physician's office laboratory practice. One set of regulations should be adopted as the standard of practice for *all* laboratories. The applicability of each provision would depend upon the particular circumstances of practice in each physician's office laboratory. The application of the regulations should assure quality laboratory service to the consumer. AMT believes that any hasty decisions to apply current Medicare or hospital regulations to physician's office laboratory practice may jeopardize the ongoing services physicians now offer their patients.

E. *In-House Testing or Using Reference Labs*

If the scope of the service that the physician's office laboratory provides has been established by the physician(s), and this is in keeping with the type of staff, equipment and space available, additional tests falling outside these parameters should be referred to a reference laboratory.

It is incumbent on the physician to carefully screen/investigate the reference laboratory that will be utilized for this purpose.

In addition, the physician(s) and the laboratory personnel should be instructed by the reference lab as to:

1. How the specimen is to be collected
2. How the specimen is to be shipped/transported
3. Any other special instructions that may be applicable to the specific testing to be performed.

Such services should be appropriately compensated, an arrangement which would encourage physicians to utilize reference laboratories for many of the tests they require and still remain economically responsible to the patient. While some abuse has been noted in physician mark-up of fees, current drawing fees simply force physicians to perform tests in-house rather than using reference labs.

CONCLUSION

AMT reaffirms that *all* laboratories should operate under one set of regulations with accommodations for the special circumstances found in physician's office laboratories. In all cases, safeguards must insure that quality laboratory service is provided to the consumer.

**Approved by the American Medical Technologists Board of Directors, April, 1986**